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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,200	04/09/2004	David Lentz	760-129 DIV/CIP/CON II	2373
23869	7590	05/25/2006	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/822,200	Applicant(s) LENTZ ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-49 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 29-34 and 37-49 is/are rejected.
 7) ☒ Claim(s) 35 and 36 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 29-44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for “radial tensile strength of *at least about* 0.48 kg/mm²” or “elongation of *at least about* 690%”. Although 0.48 kg/mm² and 690% are given as examples, there is no support that the requirements must be > or = to 0.48 kg/mm² and 690%.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 32, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31 and 43 recite the limitation "said first ePTFE tube" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to recite, --said first ePTFE tubular structure--.

Claim 32 recites the limitation "said self-sealing material" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to recite, --said self-sealing gel--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-31, 40-43, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Okita (US 4,193,138, cited in IDS). Okita discloses a multilayer ePTFE graft (col.3, lines 44-50; tube 1 has multiple layers of different fibril structure; see fig.6) comprising a first ePTFE tubular structure (inner thickness of tube 1 near 11) having a first internodal distance (see fig.6; near 11), a second ePTFE tubular structure (outer thickness of tube 1 near 10) having a second different internodal distance (fig.6, near 10), disposed about the first tubular structure, and a self-sealing gel (13) of the group claimed (celluloses; col.4, lines 12-24) interposed between the two tubular structures (see fig.6). Okita discloses nodal distance greater on the first tubular structure (col.8, lines 31-40). Okita discloses a flowable form (gelled or soluble polymers; col.7, lines 26-

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30, 60-65; col.8, lines 9-12). Biodegradable is an inherent property of celluloses. Referring to claims 47-49, these are inherent properties of the materials used, Okita has disclosed the same materials as used by the applicant.

Claims 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al (US 4,816,339, cited previously). Tu discloses a multilayered ePTFE graft (col.2, lines 6-10; fig.2) comprising a first ePTFE tubular structure (luminal layer) having a first internodal distance, a second ePTFE tubular structure (second layer) having a second different internodal distance (col.2, lines 43-55), disposed about the first tubular structure (fig.2). Tu's graft inherently possesses the same properties of elongation and strength claimed, since the same material of the applicant is used, ePTFE having the same internodal distance used by the applicant (col.2, lines 43-55; col.5, lines 22-28), sinter temperature (see examples), etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-34, 37-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. (US 6,383,214 B1) in view of Buirge et al. (US 6,391,052 B2). Referring to claims 29, 41, 45, 46, and 49, Banas discloses a multilayer ePTFE graft (see all figs) comprising two ePTFE tubular structures (24, 26; col.1, lines 8-12) disposed upon one another, each having

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different internodal distances (col.13, lines 30-35). Banas also discloses an adhesive sealing material (col.5, lines 5-8, 32-37) interposed between the two tubular grafts (24, 26), however does not disclose the particular adhesive sealing material claimed (collagens, celluloses, etc). Buirge teaches in the same field of multilayered grafts, the use of a collagen gel as an alternative sealing adhesive to bond two tubular graft (12, 13; fig.7) structures to one another (col.7, lines 37-42; col.8, lines 10-13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Banas's multilayer graft with sealing adhesive, with Buirge's teaching of using an alternative adhesive, collagen gel, to bond two tubular grafts together. It is noted that the sealing ability (leakage) is an inherent property of the sealing material (collagen gel), and will perform the function, since the same material is used as the applicant.

Referring to the remaining claims, see Banas figures. Particularly with respect to claim 32, the "material" is being considered on the ePTFE tubular structures, being a fluoropolymer. With respect to claim 37, the gel (adhesive) when applied, will inherently soak into the pores of the ePTFE, thus be impregnated.

Allowable Subject Matter

Claims 35-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

It is also noted, that if the claimed "self-sealing material" in claim 32 were distinguished to be *in addition* to the gel *and* two tubular structures (therefore, the thermoplastic or

fluoropolymer could not be considered to be one of the two ePTFE tubular structures), claims 32 and 34-39 would also be allowable in the objectable form.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

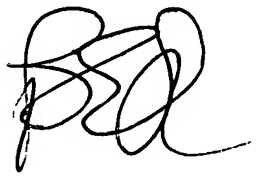
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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PRIMARY EXAMINER